Docket No.: 341148020US

(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:
J. Nelson Wright et al.

Application No.: 10/750,164

Confirmation No.: 5009

Filed: December 31, 2003

Art Unit: 3737

For: MARKER LOCALIZATION SENSING SYSTEM SYNCHRONIZED WITH RADIATION SOURCE

Examiner: James M. Kish

**REPLY BRIEF UNDER 37 C.F.R. § 41.41**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As required under § 41.37(a), this Reply Brief is filed two months from the mailing of the Examiner's Answer from the Appeal Brief. This Reply Brief responds to the Examiner's Answer mailed on December 10, 2007 in the above-identified application, and is in furtherance of the Notice of Appeal filed on June 5, 2007, and the Appeal Brief filed on September 14, 2007.

I. STATUS OF CLAIMS

A. Total Number of Claims in Application

There are 15 claims pending in the application.

B. Current Status of Claims

1. Claims canceled: none

2. Claims withdrawn from consideration but not canceled: none

3. Claims pending: 1-15

4. Claims allowed: none

5. Claims rejected: 1-15

C. Claims On Appeal

The claims on appeal are claims 1-15.

## II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 1, 6 and 11 are unpatentable over claims 1 and 6 of U.S. Patent No. 7,026,927 ("the '927 patent") under the doctrine of obviousness-type double patenting.

B. Whether claims 1, 2, 4-7, 9-12, 14 and 15 are unpatentable over U.S. Patent Application No. 2002/0193685 to Mate et al. ("Mate") under 35 U.S.C. § 103(a).

C. Whether claims 3, 8 and 13 are unpatentable over Mate in view of U.S. Patent No. 5, 729,129 to Acker et al. ("Acker") under 35 U.S.C. § 103(a).

## III. ARGUMENTS IN REPLY TO EXAMINER'S ANSWER

### A. Rejections Under the Doctrine of Obviousness-Type Double Patenting

Applicants appreciate Examiner's withdrawal of this rejection.

B. Rejections Under 35 U.S.C. § 103(a) are improper

Applicants refer to the legal standards for obviousness as summarized in its Appeal Brief. Under these legal standards, the applicants' invention would not have been obvious. The Examiner does not identify prior art references, or a combination thereof, that disclose all the elements of the pending claims. Moreover, the Examiner has failed to identify a sufficient reason why a person of ordinary skill in the art would find the claimed invention obvious over Mate, or Mate in combination with Acker. Therefore, the claims on appeal should be allowed.

Applicants further refer to the additional arguments made in its Appeal Brief, which will not be repeated herein, but which the applicants continue to maintain in view of the Examiner's Answer.

For the reasons explained below, the §103 rejection of these claims is not proper as Mate alone, or Mate in combination with Acker fails to teach or suggest all of the claimed features. The Examiner concludes that Paragraph 53 "describes a method for removing data that has been corrupted by an excitation source." The applicants respectfully disagree. Paragraph 53 of Mate states that the "marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways" in order to allow the receiver to differentiate between the marker signal and the excitation source. (Mate, [0053]) The marker's excitation signal and response signal are being differentiated; corrupted data is not being removed as stated by the Examiner. The Examiner then concludes that "broadly interpreted, this is describing filtering of relevant data from noise from an outside source." Again, the applicants respectfully disagree. The marker's excitation signal is being separated from the marker's response signal in order to locate the marker. Mate does not teach, suggest, or disclose a method for generating a subset of inputs by discarding corrupted input from the plurality of inputs; rather, Mate is silent with regard to corrupted data.

1. Claim 1 includes a receiver that receives a plurality of inputs, a sensor configured to receive the inputs and a correlation processor for analyzing the inputs and generating a subset of the plurality of inputs by discarding corrupted input

The claims recite a receiver and methods for use in receiving a plurality of inputs indicative of a sensed magnetic flux induced by a marker, wherein the marker is excited by an excitation source. As explained in more detail below, claim 1 recites a correlation processor for generating a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs; claims 6 recites a correlation processor for discarding selected data from the plurality of inputs to generate a subset of the plurality of inputs; and claim 11 recites a correlation processor discarding corrupted inputs subject to interference from the therapeutic radiation source from the plurality of inputs to create a subset of the plurality of inputs.

As described in the Specification and as further supported by the Figures, sense coils 302 each provide a signal to a respective amplifier 404. The amplifier 404 then provides the amplified signal to an associated analog to digital (A/D) converter 502 that converts the analog amplified signal into a digital representation. The receiver 208 will act on the plurality of digital inputs to substantially eliminate noise, interference and other "non-signal" effects to provide a plurality of high signal-to-noise ratio (SNR) digital outputs. The receiver may further include a matched filter or other device (designated as radiation detector 512 in Figure 5) that can detect the presence of interference due to the operations of the radiation delivery apparatus or any other interfering device that operates in a pulsed mode. If such interference is detected, then the receiver 208 is operative to discard received input signals from the coils 302 that occurred in that time frame.

The receiver 208 further includes a correlation processor 504, which may analyze the plurality of inputs in a coherent manner and may generate a subset of the plurality of inputs by discarding corrupted inputs from the plurality of inputs. Corrupted inputs are

acquired when a therapeutic radiation source (shown as incoming arrow) is detected as active by radiation detector 512.

2. Mate Discloses a Target Locating and Tracking System, Having One or More Excitable Markers, an External Excitation Source, a Plurality of Sensors, and a Computer Coupled to the Sensors and Configured to Identify a Target Isocenter.

Mate is directed to a system for locating a target associated with a patient. The system includes one or more excitable markers positionable in or near the target. The system also includes an external excitation source that remotely excites the markers to produce an identifiable signal, and a plurality of sensors spaced apart in a known geometry. The system further includes a computer coupled to the sensors and configured to use the marker measurements to identify a target isocenter within the target and compare the position of the target isocenter with the location of the machine isocenter. (Mate, abstract). Mate discloses a system that allows the target's actual position relative to the machine isocenter to be monitored during the radiation therapy so as to minimize collateral damage to healthy tissue surrounding the target. (Mate, [0035]). Mate further discloses differentiating the marker's response signal from the marker's excitation signal. (Mate, [0053]).

Applicants believe that the Examiner continues to incorrectly misconstrue paragraphs 0053 and 0054 of Mate; for reference, these two paragraphs are provided below:

> [0053] The marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways. In one embodiment, the excitation source 32 is turned or gated "on" to excite the marker and then turned or gated "off" to allow for measurement of the marker response without interference by the signal from the excitation source. The marker 30 will continue to resonate after the excitation source 32 is gated "off" for a period determined by the sensor's electric inductance, capacitance and series resistance. In another embodiment, the system is operated in continuous wave (CW) mode where the excitation source 32 remains "on" during measurement of the markers 30. The marker signal is 90 degrees "out of phase" with the signal from the

excitation source, so the marker signal is removed from the excitation signal. The time of the zero crossing of the excitation signal is known and the remaining marker signal will be at its peak intensity at that time. In a third embodiment, the output frequency of the excitation source's signal is continuously varied or scanned to maximize the excitation of the markers 30 which results in a maximum marker signal while minimizing or eliminating unwanted excitation signal.

[0054] The position of each marker 30 relative to the target 12 and relative to the target isocenter 40 is also calculated or determined. In one embodiment, the target isocenter 40 in the target 12 is chosen first based upon imaging data about the target provided by an imaging system, such as a CT scan, MRI, ultrasound system, or nuclear imaging system (e.g. positron emission tomography). Once the target isocenter 40 is selected, the position of each implanted marker 30 is measured relative to the target isocenter 40. The position of the target isocenter 40 is then determined relative to the reference coordinate system 72 based upon defining the location of each marker 12 relative to the reference coordinate system.

In the Final Office Action and again in the Examiner's Answer, the Examiner states that Paragraph 53 "describes a method for removing data that has been corrupted by an excitation source." The applicants respectfully disagree. Paragraph 53 of Mate states that the "marker signal may be separated from the signal generated by the excitation source 32 via signal processing software or electronics in a number of ways" in order to allow the receiver to differentiate between the marker signal and the excitation source. (Mate, [0053]). The marker's excitation signal and response signal are being differentiated; corrupted data is not being removed as stated by the Examiner. The Examiner then concludes that "broadly interpreted, this is describing filtering of relevant data from noise from an outside source." In the Examiner's Answer, the Examiner states "[t]he plurality of inputs discussed in the independent claims can be interpreted as a signal portion and a noise portion. The generation of a subset of the plurality of inputs can be interpreted as filtering the signal out of the noise ...." Again, the applicants respectfully disagree. The marker's excitation signal is being differentiated from the marker's response signal (both of which are within the control of Mate) in order to locate the marker. Mate does not teach, suggest, or disclose a method for discarding input which has been corrupted by an incoming radiation signal. Thus, the Board should reverse the Examiner's rejections.

3. Mate Fails to Support a Prima Facie Case for Rejecting Claim 1 Under Section 103 for at Least the Reason that His Reference Fails to Disclose or Suggest Generating a Subset of the Plurality of Inputs.

Mate fails to support a *prima facie* case for rejecting claim 1 under Section 103 for at least the reason that this reference fails to disclose or suggest generating a subset of the plurality of inputs. Independent claim 1 recites (**a**) generating a subset of the plurality of inputs by (**b**) discarding corrupted inputs from the plurality of inputs, wherein (**c**) inputs that are acquired when a therapeutic radiation source is active are considered corrupted. Mate is silent with respect to a therapeutic radiation source signal. Mate discloses separating the marker signal from the signal generated by the excitation source. This separation of the marker signal from the source signal is accomplished in order to discern the marker signal separate from the excitation signal in order to localize the marker. The claimed invention is directed to an improvement to Mate by further addressing the issue of removing corrupted input, which is defined as input acquired when a therapeutic radiation source is active. In this regard, applicants believe that the Examiner fails to appreciate that the excitation source and the therapeutic radiation source are distinct issues when solving the problem of locating and tracking a marker signal. When a therapeutic radiation source is present, *both* issues must be addressed. Applicants respectfully disagree with the Examiner's conclusory statement on page 5 of his Answer that indicates that Mate recognizes noise from "whatever source" must be accounted for. In fact, Mate is silent with respect to input from the therapeutic radiation source.

Applicants agree that Mate discloses separating the marker signal from the signal generated by the excitation source, but applicants failed to understand how the claimed method of discarding corrupted inputs (defined as inputs that are acquired when a therapeutic radiation source is active) was rendered obvious by the separation of a source signal from the marker signal as taught by Mate until reading the following statement by the Examiner from his Answer:

> "Regarding the same issue of excitation source versus therapeutic radiation source it is noted that the excitation source is a form of radiation. The system and

method disclosed by Mate is therapeutic. Therefore, the Examiner interpreting a "therapeutic radiation source" broadly includes the excitation source as a therapeutic radiation source because without localizing the marker within the patient the therapy provided by Mate could not function properly. Therefore, the excitation source is an integral portion of the therapy process and can, and has been, interpreted as a therapeutic radiation source." (Examiner's Answer, page 7)

Given this statement, applicants can understand the basis for the Examiner's erroneous conclusions. Accordingly, applicants wish to clarify that as is known in the art, "therapeutic radiation" refers to the medical use of ionizing radiation, typically as part of a cancer treatment to control malignant cells. The therapeutic radiation source is an ionizing radiation device, known as a linear accelerator. (Mate, [0034, 0059]) Generally, as is also known in the art, electromagnetic radiation is classified into types according to the frequency of the wave. The excitation source of Mate operates within a frequency range to be considered non-ionizing radiation. (Mate, [0045]) Non-ionizing radiation refers to any type of electromagnetic radiation that does not carry enough energy per quantum to ionize atoms or molecules (e.g. to completely remove an electron from an atom or molecule). Instead of producing charged ions when passing through matter, the electromagnetic radiation has sufficient energy only for excitation (the movement of an electron to a higher energy state). Therefore, the Examiner's reasoning and resulting conclusion are in error. The "therapeutic radiation source" cannot be broadly construed to include the excitation source as a therapeutic radiation source, and therefore, the disclosure of Mate does not render the claimed invention obvious.

Additionally, in the Examiner's Answer, the Examiner incorrectly characterizes the "input" recited in the claims as a signal portion and a noise portion. (Examiner's Answer, page 8) This interpretation ignores the recited language of the claims which states that the corrupted inputs are discarded and the corrupted inputs are defined as inputs that are acquired when a therapeutic radiation source is active. The Examiner provides no basis for interpreting the input as having a signal portion and a noise portion.

The Examiner further asserts that "[r]egardless of whether the source is the actual excitation source or a therapeutic source, it would be obvious to one of skill in the art to remove erroneous data from a localization signal in order to localize the target correctly." Such reasoning is simply a conclusion and does not satisfy the established guidelines or recent directives. Contrary to the Examiner's assertion, there are numerous and significant differences between the pending claims and the applied references. The claimed invention is drawn to removal of data input in its entirety if the input was generated while a therapeutic radiation source is active. Mate discloses differentiating between an excitation signal and a response signal. The Examiner's merely conclusory statement fails to provide a reasoned statement for why one skilled in the art would generate a subset of the plurality of inputs by discarding corrupt inputs, wherein the inputs that are acquired when the therapeutic radiation source is active are considered corrupted.

These differences are not such that the subject matter of claim 1 as a whole would have been obvious to a person of ordinary skill in the pertinent art. This is true for at least the reason that such a person would not have found it obvious to consider the teachings of Mate to arrive at a receiver that receives a plurality of inputs that includes (**a**) generating a subset of the plurality of inputs by (**b**) discarding corrupted inputs from the plurality of inputs, wherein (**c**) inputs that are acquired when a therapeutic radiation source is active are considered corrupted. The Examiner asserts that it would have been an obvious matter of design choice "to remove erroneous data from a localization signal in order to localize the target correctly." Applicants disagree. The Examiner continues to rely on conclusory statements and has failed to articulate a reasoned statement for why someone skilled in the art would know that data was corrupted or how, once identified, it would be removed. Further, the Examiner has failed to supply a reference or reasoned statement for designating input "acquired when a therapeutic radiation source is active" as corrupted as claimed. Applicants respectfully submit that the only motivation for generating a subset by discarding corrupt data is found in the claimed invention, and thus, the Examiner has not satisfied the obviousness standard.

4. Response to Section 103 Rejections under Mate in view of Acker

Claims 3, 8 and 13 are patentable over Mate in view of Acker for a number of reasons. One reason the Section 103 rejection of these claims is not proper because the cited references fail to teach or suggest all of the claimed features. For the reasons explained above, Mate fails to teach or suggest generating a subset of the plurality of inputs. The Examiner does not cite Acker to correct the deficiencies of Mate. Applicants agree that Acker does not correct the deficiencies of Mate. Rather, the Examiner cites Acker to teach the matched filter for detecting interference, this does not teach or suggest generating a subset of the plurality of inputs. Therefore, the Examiner has not established a *prima facie* case of obviousness with regard to dependent claims 3, 8 and 13, which depend from allowable independent claims.

A further reason that the Section 103 rejection is improper is that modifying the Acker invention with the filter of the claimed invention will render the Acker invention inoperable for its intended purpose. Specifically, Acker discloses and teaches an analog or digital band pass filter that is not equivalent to a matched filter. For example, the analog or digital band pass filter disclosed in Acker is an in-line filter designed to reject interference. The claimed matched filter is a separate off-line filter to detect interference. Adding the filter of Acker to Mate would not yield the claimed invention. Neither Acker nor Mate teach or suggest providing a separate off-line filter to detect interference. Yet another reason that the Section 103 rejection is improper is that under the statutory language of § 103(a), as analyzed according to the framework set forth by the Supreme Court, claims 3, 8 and 13 are nonobvious to a person of ordinary skill in the pertinent art.

Acker fails to cure the deficiencies of Mate in order to support a Section 103 rejection of claims 3, 8 and 13. Furthermore, since claims 3, 8 and 13 depend from otherwise allowable independent claims 1, 6 and 11, the Section 103 rejections of these dependent claims are improper for the reasons discussed above and for the additional

features of these claims. Accordingly, the Board should reverse the Examiner's rejection of these claims.

## IV. CONCLUSION

Each of pending claims 1-15 has been improperly rejected for numerous reasons. One reason is that the applied references do not teach or suggest all of the features of each of claims 1-15. Therefore, the Examiner has failed to make a *prima facie* case of obviousness of each claim, and the Examiner thus cannot reject the claims under § 103(a). Each pending claim has been improperly rejected for at least the additional reason that each pending claim is nonobvious to a person of ordinary skill in the pertinent art under the statutory language of 35 U.S.C. § 103(a), as analyzed according to the framework set forth by the Supreme Court. Accordingly, the Board should reverse the Examiner's rejections of pending claims 1-15.

The Commissioner is hereby authorized to charge any shortages or credit any overpayment associated with this filing to our Deposit Account No. 50-0665, under Order No. 249768011US1 from which the undersigned is authorized to draw

Dated: 2.11.08

Respectfully submitted,

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